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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of	: PIEPER, M. P. ET AL	) Art Unit:	1645
U.S. Appln. No.	: 10/625,129	) Examiner:	

Confirmation No.: 8804 U.S. Filing Date: 07/23/2003

Title of Invention: Pharmaceutical Compositions for Inhalation Containing an

Anticholinergic, Corticosteroid, and Betamimetic

Attny. Docket No.: 1/1382

Mail Stop Amendment Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

July 20, 2004

## TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

 $\boxtimes$ 

1.97(b).

Transmitted herewith concerning the subject application is an Information Disclosure Statement (Form 1449A and B) with copies of all references cited therein. This is being submitted pursuant to 37 C.F.R. §1.56 and before the mailing of a first Office Action on the merits, pursuant to 37 CFR § 1.97(b).

It should be noted that the references listed in the Information Disclosure Statement have been cited in the International Search Report (ISR) for PCT/EP 03/08222, which corresponds to the present US application. A copy of that ISR is enclosed herewith.

This Statement is being filed: i) within three (3) months of the filing

date of a national application other than a continued prosecution application under 33 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.
1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:
A statement as specified in 37 C.F.R. §1.97(e) [see below]; or

		The fee set forth in 37 C.F.R. §1.17(p).
		The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.
	ent as s	This Statement is being filed after the period specified in 37 C.F.R. on or before payment of the issue fee. This Statement is accompanied by a pecified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R.
	1.97(e	).
	counte	Each item of information contained in the instant information disclosure ent was first cited in any communication from a foreign patent office in a creat foreign application not more than three (3) months prior to the filing of that information disclosure statement; or
	foreign makin inform C.F.R.	No item of information contained in the instant information disclosure ent was cited in a communication from a foreign patent office in a counterpart application, and, to the knowledge of the person signing this certification after greasonable inquiry, no item of information contained in the instant nation disclosure statement was known to any individual designated in 37 §1.56(c) more than three (3) months prior to the filing of the instant nation disclosure statement.
		The fee set forth in 37 C.F.R. §1.17(p).
		The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.
counte in sect	erpart aption 1.50	d). Each item of information contained in the accompanying information tement was cited in a communication from a foreign patent office in a opplication, which communication was not received by any individual designated (c) more than thirty (30) days prior to the filing of the accompanying isclosure statement.

The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Triplicate copies of this form are enclosed.

Respectfully submitted,

Timothy X. Witkowski Attorney for Applicant(s)

Reg. No. 40,232

Patent Department Boehringer Ingelheim Corp. 900 Ridgebury Road, P.O. Box 368 Ridgefield, CT 06877 Tel: (203) 798-4310 Certificate of Mailing

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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PTO/SB/08a (08-03)

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RADEMAS ubstitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete if Known **Application Number** 10/625,129 Filing Date 07/23/2003 First Named Inventor Michael Paul PIEPER Art Unit 1645 **Examiner Name** 

(Use as many sheets as necessary) Attorney Docket Number | 1/1382

			U. S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2 (f known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	İ	<sup>US-</sup> 2003/018019 A1	01/23/2003	Meade, C. J. M. et al	
		<sup>US-</sup> 2003/152523 A1	08/14/2003	Martin, G. P. et al	
		<sup>US-</sup> 2002/115680 A1	08/22/2002	Meissner, H. et al	
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	FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> (Number <sup>4</sup> 'Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		WO 03/000241 A2	01/03/2003	BI Pharma KG		
	†·····	WO 01/58425 A2	08/16/2001	King S. College London		
	†************* <b>†</b>	WO 02/32899 A1	04/25/2002	BI Pharma KG		
***************************************	<b></b>					
	<b>†</b>					

Examiner	Date	
Signature	Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b (08-03)
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Examiner

Signature

JUL 2 2 2004

TRANSMITUTE for form 1449B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Application Number 10/625,129 Filing Date 07/23/2003 First Named Inventor Michael Paul PIEPER Art Unit 1645 Examiner Name Attorney Docket Number 1/1382 2

Complete if Known

	NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		DUTU, S. ET AL; Lung Function In COPD Patients Under Long Term Inhaled Therapy With Bronchodilator Agents and Beclometasone", European Respiratory Journal, Supp., Bd. 10, Nr. 25, Supp. 20, 1997; XP001147945	
		BALZANO, G. ET AL; "Effectiveness and Acceptability of a Domiciliary Multidrug Inhalation Treatment in Elderly Patients with Chronic Airflow Obstruction: Metered Dose Inhaler Versus Jet Nebulizer"; J. of Aerosol Medicine, Vol. 13, No. 1, 2000, pgs. 25-33, XP001078735	
			<u> </u>

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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